INTERNATIONAL STANDARD

ISO 15883-4

First edition
2008-05-01

Washer-disinfectors —

Part 4: Requirements and tests for washer-disinfectors employing chemical disinfection for thermolabile endoscopes

Laveurs désinfecteurs —

Partie 4: Exigences et essais pour les laveurs désinfecteurs destinés à la désinfection chimique des endoscopes thermolabiles

Reference number
ISO 15883-4:2008(E)

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Published in Switzerland

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Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 2.

The main task of technical committees is to prepare International Standards. Draft International Standards adopted by the technical committees are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75 % of the member bodies casting a vote.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights.

ISO 15883-4 was prepared by Technical Committee ISO/TC 198, *Sterilization of health care products*.

ISO 15883 consists of the following parts, under the general title *Washer-disinfectors*:

— *Part 1: General requirements, terms and definitions and tests*

— *Part 2: Requirements and tests for washer-disinfectors employing thermal disinfection for surgical instruments, anaesthetic equipment, bowls, dishes, receivers, utensils, glassware, etc.*

— *Part 3: Requirements and tests for washer-disinfectors employing thermal disinfection for human waste containers*

— *Part 4: Requirements and tests for washer-disinfectors employing chemical disinfection for thermolabile endoscopes*

— *Part 5: Test soils and methods for demonstrating cleaning efficacy*

Introduction

It is recommended that this introduction be read in conjunction with the introduction to ISO 15883-1.

The washer-disinfectors specified in this part of ISO 15883 are intended to process devices which can be immersed in water or aqueous solutions. For some devices this will require that, prior to processing, relevant parts of the device are protected from immersion in accordance with the device manufacturer's operating instructions.

Fields of application within the scope of the ISO 15883 series include laboratory, veterinary, dental and pharmaceutical applications and other specific applications, such as washer-disinfectors for bedsteads and transport carts and the disinfection of crockery and cutlery intended for use with immunologically compromised patients.

Requirements for washer-disinfectors for other applications are specified in other parts of ISO 15883.

Safety requirements for washer-disinfectors are given in IEC 61010-2-040.

With respect to the potential adverse effects on the quality of water intended for human consumption caused by the washer-disinfectors:

a) note that, until verifiable European criteria are adopted, existing national regulations concerning the use and/or the characteristics of the washer-disinfectors remain in force;

b) this part of ISO 15883 provides no information as to whether the washer-disinfectors may be used without restriction in any of the member states of the EU or EFTA.

Washer-disinfectors —

Part 4: Requirements and tests for washer-disinfectors employing chemical disinfection for thermolabile endoscopes

1 Scope

This part of ISO 15883 specifies the particular requirements, including performance, for washer-disinfectors (WDs) that are intended to be used for cleaning and chemical disinfection of thermolabile endoscopes.

This part of ISO 15883 also specifies the performance requirements for the cleaning and disinfection of the washer-disinfector and its components and accessories which may be required to achieve the necessary performance.

The methods, instrumentation and instructions required for type testing, works testing, validation (installation, operational and performance qualification on first installation), routine control and monitoring and re-validation, periodically and after essential repairs, are also specified.

NOTE 1 In addition, Annex A gives guidance on an appropriate division of responsibility for the range of activities covered by this part of ISO 15883.

NOTE 2 WDs complying with this part of ISO 15883 can also be used for cleaning and chemical disinfection of other thermolabile re-usable medical devices for which the device manufacturer has recommended this method of disinfection.

WDs complying with the requirements of this part of ISO 15883 are not intended for cleaning and disinfection of medical devices, including endoscopic accessories, which are heat stable and can be disinfected or sterilized by thermal methods (see ISO 15883-1:2006, 4.1.5).

The specified performance requirements of this part of ISO 15883 may not ensure the inactivation or removal of the causative agent(s) (prion protein) of transmissible spongiform encephalopathies.

NOTE 3 If it is considered that prion protein might be present, particular care is needed in the choice of disinfectants and cleaning agents to ensure that the chemicals used do not react with the prion protein in a manner that may inhibit its removal or inactivation from the load or washer-disinfector.

This part of ISO 15883 can be used by prospective purchasers and manufacturers as the basis of agreement on the specification of WD manufacturers of endoscopes, cleaning products, disinfecting products, and also by users.

2 Normative references

The following referenced documents are indispensable for the application of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO 11731-2, *Water quality — Detection and enumeration of Legionella — Part 2: Direct membrane filtration method for waters with low bacterial counts*

ISO 15883-1:2006, *Washer-disinfectors — Part 1: General requirements, terms and definitions and tests*

ISO/TS 15883-5:2005, *Washer-disinfectors — Part 5: Test soils and methods for demonstrating cleaning efficacy*

IEC 61010-2-040, *Safety requirements for electrical equipment for measurement, control, and laboratory use — Part 2-040: Particular requirements for sterilizers and washer-disinfectors used to treat medical materials*

3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 15883-1 and the following apply.

3.1
air break
physical separation in water supply pipes to prevent back syphonage into the water supply from a device connected to it

NOTE See EN 1717.

3.2
inoculated carrier
supporting material on or in which a defined number of viable test organisms has been deposited

[ISO 11138-1:2006, definition 3.10]

3.3
leak test
test intended to establish that the surface covering the device and/or lining a device channel is intact to the extent necessary to maintain a slightly positive pressure

3.4
liquid transport systems
those components of the washer-disinfector used to store, pump or transport water and/or solutions within the washer-disinfector, excluding pipework before the air break

3.5
microbial inactivation factor
measured change in microbial population, expressed as $\log_{10}$, caused by the lethal effect of the disinfectant

3.6
microbial reduction factor
measured change in microbial population expressed as $\log_{10}$ caused by the combination of the microbial inactivation factor and the physical removal of microorganisms

3.7
obstruction
partial or complete blockage

3.8
self-disinfection cycle
operating cycle under the control of the automatic controller, for use without any load in the washer-disinfector, which is intended to disinfect all liquid transport systems' piping, chamber(s), tanks and other components which come into contact with the water and/or solutions used for cleaning, disinfecting and rinsing the load

NOTE This does not include disinfection of any pipework between the disinfectant supply and the control valve, where single-use, multi-dose containers are used to provide process chemicals for use in the washer-disinfector.

3.9
thermolabile
damaged by exposure to temperatures within the range used for thermal disinfection

NOTE The minimum temperature for thermal disinfection specified in ISO 15883-1 is 65 °C.

4 Performance requirements

4.1 General

4.1.1 The WD shall conform to ISO 15883-1:2006 with the exception of the following subclauses:

— 4.2.3 (washing stage);

— 4.3.1 (specification for thermal disinfection);

— 5.3.2.5 (microbial quality of final rinse water);

— 6.4.2 (test for quality of final rinse water);

— 6.5.6 (test for chamber venting to prevent pressurization by steam);

— 6.7.2 (tests on trolleys for handling loads outside the WD);

— 6.8.2 (load temperature test);

— 6.10 (cleaning efficacy test; 6.10.2 modified by 6.11 of this part of ISO 15883).

NOTE These subclauses have been replaced or modified in this part of ISO 15883.

4.1.2 Each device, including any device channels and/or cavities, shall be processed by the WD as follows:

a) leak testing (where appropriate) in accordance with 4.2;

b) cleaning (which may include several stages) in accordance with 4.3;

c) disinfecting in accordance with 4.4;

d) final rinsing in accordance with 4.5;

e) purging of rinse water in accordance with 4.6;

f) drying (when appropriate) in accordance with 4.7.

4.1.3 After the complete process in the WD the endoscope shall be free from vegetative bacteria (but not necessarily spores) and other contamination. The combination of the cleaning process and the disinfection process shall be designed to achieve this condition, recognising the high level of bacterial contamination that may exist, see Bibliography [24], [25] and [26]. It shall be necessary to take into account other factors such as the design of connectors. The WD manufacturer shall demonstrate this capability during type testing for all the types of endoscope that the WD is designed to process.

NOTE 1 Demonstration of the capability of the complete cycle may be provided during type testing by employing a modification of the method described in Annex B, using the organism previously established as most resistant to the disinfectant, with real endoscope(s) and/or the method given in ISO/TS 15883-5:2005, Annex I.

NOTE 2 The efficacy of the process (including cleaning and disinfection) depends on a number of factors which include

a) the nature (characteristics) of the device being processed;

b) the extent and nature of the soiling to be removed;

c) the temperature;

d) the mechanical energy (type, output);

e) purging to remove rinse water;

f) the detergent system;

g) the nature, volume, concentration and temperature of the cleaning and disinfectant solutions and their ability to wet the surfaces to be cleaned and disinfected;

h) the duration of the various process stages;

i) the removal of suspended soil.

4.1.4 The WD manufacturer's instructions shall recommend that any requirements, e.g. for manual cleaning and or disassembly of the endoscope, prior to processing in the WD, provided by the device manufacturer should be followed.

4.1.5 The value of any process variable that affects the efficacy of the cycle shall be pre-set and adjustment shall require the use of a key, code or tool (see also ISO 15883-1:2006, 5.18.3, 5.18.8 and 5.18.12).

4.1.6 The means to control the volume of process chemicals admitted shall deliver the set volume to an accuracy of ± 5 % or better.

4.1.7 When the WD uses two or more different process chemicals, means shall be provided to ensure that connection is made to the correct container of process chemical.

NOTE The labelling and/or colour coding of connectors, containers and/or tubes alone may not be sufficient to meet the requirement.

4.1.8 The WD manufacturer's instructions shall recommend that heat-stable endoscopic accessories to thermolabile devices should be thermally disinfected and/or sterilized. [See 8 j) and ISO 15883-1:2006, 4.1.5].

4.2 Systems for leak testing

4.2.1 The requirements of 4.2 shall apply only to WDs intended to process endoscopes which require a test to verify that the device is watertight.

NOTE This test is intended to demonstrate that the endoscope will not be damaged by liquid ingress during the WD operating cycle. It is regarded only as a test of the integrity of the endoscope when all parameters of the WD leak test (e.g. pressure, duration, maximum leak accepted) are consistent with those specified by the endoscope manufacturer.

4.2.2 The WD shall be provided with either

a) means to carry out an automatic leak test on the endoscope which shall be completed before the load comes into contact with process fluids in the WD

or

b) instructions for use that include the requirement to carry out the test manually prior to processing through the WD.

NOTE 1 An alternative method specified by the endoscope manufacturer can be used for determining the integrity of the endoscope when appropriate.

NOTE 2 WDs with an automatic leak test can include a user selectable option to repeat the leak test at the end of the process and/or independently of a normal process cycle.

4.2.3 For WDs having an automatic leak test, the automatic controller shall prevent the continuation of the operating cycle and operate an audible and visible alarm indicating a leak test failure if a leak is detected in an endoscope.

Variations in temperature may adversely affect the sensitivity of the leak test and the WD manufacturer should state the temperature range permitted in the WD during the automatic leak test, if fitted [see 8 f)].

NOTE 1 A leak test failure indicates that the device is likely to be damaged by further processing; a satisfactory leak test does not provide absolute assurance that the device will not be damaged by further processing.

NOTE 2 An automatic leak test which maintains a positive pressure throughout the cycle can provide an additional safety level.

4.2.4 In WDs provided with an automatic leak test:

— the systems for connection of the device to the WD shall be designed so that the fittings provided by the WD manufacturer and intended for irrigation of the endoscope channel(s) cannot be connected to the endoscope leak test connector;

— the connection system between the endoscope and the WD shall be designed so that the leak test connector on the WD cannot be connected to the endoscope channel(s) to be irrigated;

— the means used to monitor the pressure inside the device (e.g. pressure transducer) shall be independent from the means used to control the initial pressure (e.g. pressure regulating valve);

— the system used to pressurize the device during each leak test shall be provided with a means of preventing over-pressurization of the device in the event of failure of the pressure control system;

— the extent and duration of pressurization and the pressure drop or air flow which will be used to indicate a failure shall be either in accordance with the device manufacturer's instructions for the devices which the WD is intended to process, or independently verified by the WD manufacturer.

4.2.5 For WDs with an automatic leak test, means shall be provided to automatically warn the user with an audible and/or visible alarm after the initiation of the operating cycle if the leak test connectors were not connected to the endoscopes.

4.2.6 WDs with an automatic leak test shall be tested in accordance with 6.5.

4.3 Cleaning

4.3.1 General

All surfaces (internal and external) of the endoscope(s) which are required to be disinfected by the WD shall be cleaned. (See ISO 15883-1:2006, 4.2.1.1, 5.1.10 and 6.10.2).

NOTE Some endoscope(s) have component parts (e.g. electronic connectors) which their manufacturer recommends should not be immersed in water or aqueous solutions. These component parts will be processed in accordance with the manufacturer's instructions and then protected from immersion during processing in the WD (see 5.1.2).

Cleaning shall comprise washing with a detergent solution which may, when necessary, be preceded by flushing. Washing shall be followed by rinsing unless the conditions specified in 4.3.4 have been met.

4.3.2 Flushing

When necessary, the WD shall provide means to flush the internal and external surfaces of the endoscope.

NOTE Flushing before washing might be necessary to eliminate soils or to avoid any interaction between the chemicals used during pre-treatment and those of the WD processing cycle.

The flushing water or solution shall be discharged during or after each process cycle and shall not be re-used.

4.3.3 Washing

The WD manufacturer shall specify the detergent(s) to be used, as established during type testing [see 8 m)].

The detergent solution shall be discharged during or after each process cycle and shall not be re-used.

The temperature of the detergent solution throughout the washing stage shall be monitored to ensure that it remains within the limits specified by the manufacturer of the detergent and be compatible with the temperature limits for the device(s) to be processed.

This shall be achieved either

a) by controlling the temperature of the detergent solution

or

b) where appropriate, by operating the WD at ambient temperature with a means of preventing operation of the WD when the detergent temperature is outside the specified temperature range.

4.3.4 Post-washing rinsing

Rinsing between washing and disinfection shall be used to reduce the concentration of residues (process chemicals and soiling including microbial contamination) to a level established as not exceeding that which would impair the efficacy of the disinfection process.

Rinsing shall take place between washing and disinfection unless it can be demonstrated that:

a) there is no reaction between incompatible process chemicals being used for each of these phases;

b) there is no adverse reaction between suspended or residual soiling and the disinfectant.

The interaction between the disinfectant and residual soiling shall be tested under conditions in which soiling is at or above the maximum level that may occur in use and the disinfectant is at or below the minimum specified in-use concentration.

The rinse water quality shall be specified by the WD manufacturer; this shall be of, at least, potable quality.

4.3.5 Determination of cleaning efficacy

Cleaning efficacy shall be determined in accordance with 6.11.

4.4 Disinfecting

4.4.1 General

National regulatory requirements may specify approval procedures for disinfectants to be used in WDs for medical devices. Compliance with these national requirements shall be deemed to meet the requirements of 4.4 within the territory where these requirements apply.

The capability of the WD to provide disinfection of the device shall be deemed to have been established if, when the WD is tested as specified in 6.12.6 under the specified conditions of disinfectant concentration, volume, temperature and contact time the required microbial inactivation factor is attained (see 4.4.2.4).

The choice of disinfectant shall ensure that the spectrum of activity is appropriate for the intended use. The efficacy of disinfectants may be seriously impaired by residual soiling, inorganic salts etc. remaining on the device(s) and therefore an effective cleaning prior to disinfection is required.

NOTE Other process chemicals, e.g. detergents can react with and seriously impair the activity of disinfectants if they are not removed before the disinfection stage.

4.4.2 Efficacy of the disinfectant

4.4.2.1 The following tests are based on the use of aqueous solutions of a disinfectant. Other systems based on gaseous disinfectants are not excluded; equivalent tests are required.

4.4.2.2 When tested in accordance with 6.12.2, the *in vitro* efficacy of the disinfectant shall be demonstrated.

4.4.2.3 A specific neutralization method for the disinfectant shall be validated in accordance with 6.12.2.6.

NOTE These data can be provided by the disinfectant manufacturer.

4.4.2.4 When tested in accordance with 6.12.2 and 6.12.6 for the minimum exposure time at the minimum concentration and the minimum temperature to be used in the WD the disinfectant shall demonstrate:

a) at least a $\log_{10}6$ inactivation of vegetative bacteria including yeasts and yeast-like fungi;

b) at least a $\log_{10}5$ inactivation of mycobacteria;

c) at least a $\log_{10}4$ inactivation of fungal spores and viruses.

NOTE 1 The inactivation values specified are regarded as the minimum necessary for endoscopes; they may be different from the values specified in other standards to permit a label claim for biocidal activity.

NOTE 2 National regulatory authorities can require higher inactivation values.

4.4.2.5 The disinfectant chosen shall also be active against bacterial endospores.

When tested at the minimum concentration and the minimum temperature to be used in the WD when processing endoscopes, the disinfectant should reduce the population of bacterial spores by not less than $\log_{10}6$ within 5 h of exposure, or at an equivalent rate. The disinfectant should be tested against spores of known high resistance to the disinfectant from both aerobic and anaerobic organisms.

4.4.2.6 The experimental conditions of tests intended to demonstrate the microbicidal activity of the disinfectant *in vitro* shall consider the conditions of use of the disinfectant. Thus, when there is no rinsing between cleaning and disinfection, the disinfectant shall be tested in the presence of interfering substances (see also 4.3.4), and, for example, dirty conditions.

NOTE Demonstration by the disinfectant manufacturer that the disinfectant meets the above requirements may be made employing methods based on relevant published standards or other relevant publications (e.g. EN 13624, EN 13727, EN 14348, EN 14476, EN 14561, EN 14562, AOAC sporicidal test, ASTM E2111-00).

4.4.3 Temperature

The temperature of the disinfectant solution throughout the disinfection stage shall be monitored to ensure that it remains within the limits specified by the manufacturer of the disinfectant and be compatible with the temperature limits for the device(s) to be processed.

This shall be achieved either by controlling the temperature of the disinfectant solution or, where appropriate, by operating the WD at ambient temperature with means to prevent operation of the WD when the disinfectant temperature is outside the specified temperature range.

4.4.4 Process monitoring

The process monitoring of each operating cycle by the automatic controller shall include verification that the process conditions specified by the WD manufacturer as necessary and sufficient for disinfection to take place (e.g. disinfectant concentration, temperature and contact time) were attained (see also 5.5).

Microbial testing (e.g. with biological indicators or inoculated carriers) of the disinfection stage on each cycle shall not be used to meet this requirement.

NOTE Confirmation of the concentration of disinfectant can require e.g. measurement of the volume of disinfectant and water admitted together with a certificate of conformity from the disinfectant supplier for the concentration of the disinfectant, together with data to support the shelf life, expiry date etc. (see also 4.4.5.2).

4.4.5 Disinfectant use

4.4.5.1 General

The WD manufacturer shall specify the disinfectant(s) to be used, as established during type testing (see 8 m).

Disinfectant solutions shall either be discharged after a single use during each cycle or re-used for a limited number of cycles (see 4.4.4). Discharge after a single use, during each cycle, is the preferred option.

4.4.5.2 Re-use of disinfectant solutions

If the WD is designed to allow the same disinfectant solution to be used on two or more consecutive operating cycles then care shall be taken to ensure that the activity and safety (e.g. accumulation of foreign material, device compatibility) of the disinfectant solution is not impaired during its working life.

This shall include the following.

a) The WD manufacturer shall specify the means which shall be used to ensure that the disinfectant solution has retained the required anti-microbial activity. These means shall be based on validation studies, which would normally be carried out by the disinfectant manufacturer, to determine a suitable parameter, or parameters, which may be monitored to indicate the anti-microbial activity of the disinfectant. Suitable parameters may include e.g. pH, stability, the concentration of the active ingredient and adjuvants that may also affect performance.

NOTE Minor changes in formulation of the disinfectant can have a significant effect on storage life, anti-microbial activity etc.

b) The WD manufacturer shall recommend to the user the maximum period or number of operating cycles for which the disinfectant may be used. This shall be based on validated experimental data.

c) When validated use conditions (maximum period or number of operating cycles) are exceeded, the automatic controller shall operate an audible and visible alarm and prevent the use of the operating cycle until chemicals are changed.

The WD manufacturer should recommend that the user monitor the disinfectant concentration using a chemical indicator specific for the disinfectant to show that the disinfectant is at or above the minimum recommended concentration (see also 4.4.4).

4.5 Final (post-disinfection) rinsing

4.5.1 The chemical purity of the final rinse water used after the disinfection stage shall be in accordance with ISO 15883-1:2006, 5.3.2.5.

4.5.2 The final rinse water shall meet the requirements for microbiological quality as given in 4.9.2.2.

4.5.3 When medical devices that are intended to come into contact with the bloodstream or other normally sterile areas of the body are to be processed the level of bacterial endotoxins in the final rinse water shall be controlled and monitored within the limits specified in national regulations. (See ISO 15883-1:2006, 6.4.2.3).

4.5.4 On completion of the final rinse stage the water shall not be stored for subsequent re-use in the rinsing stage of subsequent cycles.

4.6 Purging to remove rinse water

4.6.1 The WD shall include a means of purging rinse water from the channels of the endoscope(s) at the end of the final rinse stage.

NOTE On completion of the automatic cycle the outer surface of the device should not have so much surface water that it would need to be wiped dry before use.

4.6.2 When at the end of the rinsing stage the channels of the device are purged with air to remove most of the remaining rinse water, the air shall be oil free and shall be filtered through a filter providing not less than 99,99 % arrestance to particles of 0,2 µm and larger.

4.6.3 When the WD is intended to eliminate the residual water from the channels of the endoscope it shall be tested in accordance with 6.8.

4.7 Drying

4.7.1 Either the WD shall have a user selectable drying stage, or the instructions for use shall indicate that the device and the channels of the device shall be dried prior to storage in accordance with the device manufacturer's instructions [see 8 j), 2nd dash].

NOTE 1 Automatic cycles in which the device is not completely dried are intended for use with devices which will be used without storage. Storage of incompletely dried devices can lead to contamination with, and growth of, micro-organisms.

NOTE 2 Purging with 0,2 µm filtered alcohol (e.g. 70 % iso-propanol) can be used to aid drying, if compatible with the device.

4.7.2 The quality of air used during the drying stage shall be at least that defined in 4.6.2.

4.7.3 When tested in accordance with 6.8 there shall be no visible droplets of moisture.